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FDA Gets (Un)Social

FDA draft guidance on responding to requests for off-label information foreshadows restrictive policies on use of social media.

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The U.S. Food and Drug Administration (FDA or the Agency) closed out 2011 with the release of two important documents—(i) a draft guidance on responding to unsolicited requests for off-label information and (ii) a *Federal Register* notice requesting comments on scientific exchange in the context of investigational and off-label uses.

Despite not being focused solely on social media, the new draft guidance ventures into previously uncharted territory by addressing how organizations should respond to individual comments made in public forums—including websites and blogs (even mentioning YouTube and Twitter by name)—in addition to those made during face-to-face meetings and speaking events, suggesting that this may be the first of what FDA has indicated will be a handful of guidances addressing social media–related issues. In addition, the issuance of these documents also signals that the Agency is cognizant of, and wants to appear responsive to, ongoing industry complaints that it has provided little in the way of useful guidance on dissemination of off-label information.

Implications for Industry

Based on the newly released draft guidance for industry, titled "Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices" (the Draft Guidance), manufacturers likely will have to reconsider certain aspects of how they currently respond to requests for off-label information, particularly in the context of social media applications. These changes are likely to affect a number of operational functionalities, including the following:

- Search functions on websites and other online promotional platforms.
- Training for sales force members and medical science liaisons on how to respond to unsolicited requests for information at conferences and events.
- Speaker training on how to present information to industry for key opinion leaders and other experts hired by manufacturers who are likely to receive questions about off-label uses.
- Development of new or updated recordkeeping systems for tracking responses to unsolicited requests.

In addition to these more pragmatic implications, the Draft Guidance reveals much about what we can anticipate will become FDA's policies for the distribution of information using social media generally.

At first blush, the Draft Guidance appears unremarkable, applying FDA's long-held views and policies on responding to unsolicited requests for off-label information to social media in the same manner as it had previously applied those standards to traditional media (i.e., formalizing its stance that, in public forums, manufacturers must respond to requests for off-label information in a one-on-one venue, preventing the dissemination of the response to a broader audience). In standard public forums (e.g., medical conferences), the application of the Office of Prescription Drug Promotion's policy to require direct, one-on-one responses to public requests for off-label information would result in an absence of any response from the speaker to the audience at large. In the context of social media, however, the result of this policy view is largely *un*social, because it removes the collective aspect of the social media experience. In addition, application of this policy is more likely to open the door for responses of other discussion participants who may clutter the discussion and mislead other participants by posting inaccurate or unscientific responses. We don't know yet what FDA's views would be on a manufacturer's obligation if unrestricted (and potentially misleading) discussion were to ensue without the participation of the manufacturer.

The Draft Guidance may also have different and/or additional implications for medical device manufacturers, as their promotional and scientific exchange activities are regulated by the Center for Devices and Radiological Health (CDRH) and thus are subject to somewhat different enforcement priorities than pharmaceutical and biologic firms generally regulated by the Center for Drug Evaluation and Research (CDER).

Overview of Draft Off-Label Guidance

Solicited vs. Unsolicited

The Draft Guidance sets forth FDA's guidelines for determining whether a request is "solicited" or "unsolicited," characterizing as solicited those "requests for off-label information that are prompted *in any way* by a manufacturer or its representatives," and providing *eight* examples of contexts in which a firm would be viewed to have solicited requests for information. More than half of these examples involve new media, including tweets (i.e., microblog posts) announcing the results of investigational studies, and structuring websites to respond to searches concerning unapproved or pipeline uses. Interestingly, the Agency notes in a footnote that "in some of [these] examples, a firm's activities that serve to solicit the requests for off-label information may themselves give rise to specific regulatory violations" (i.e., the activities described in the examples may themselves violate FDA's policies). However, the Draft Guidance stops short of sorting out which of the activities in the listed examples would not comply with its policies for drug and device promotion.

Public vs. Nonpublic

The Draft Guidance also distinguishes between "nonpublic" unsolicited requests for off-label information and "public" unsolicited requests. Nonpublic unsolicited requests include communications with manufacturers in a direct, one-on-one forum, such as individual phone calls or emails. Public unsolicited requests are explained as those requests that are made in a "public forum," including both traditional live meetings and electronic venues that permit collective discussion. Of note, the concept of public forums as discussed in the Draft Guidance includes all forms of public electronic media (e.g., websites, blogs, and microblogs), whether or not such forums are sponsored by the manufacturer or a third party.

FDA's Enforcement Policy, Per the Draft Guidance

Although FDA reiterates throughout the document that it understands and appreciates the value of permitting manufacturers to respond to unsolicited requests for off-label information (whether such requests are public or nonpublic, and whether those requests are made through social media or more traditional channels), the Draft Guidance places some fairly significant burdens on manufacturers.

In the context of public requests for off-label information, for example, a firm may only respond when its product is mentioned by name in the request, and, even then, may only provide its contact information and state that the question describes an unapproved use. The Draft Guidance also states that a firm's responses to public requests should reflect the speaker's connection to the manufacturer, and may not be "promotional in tone." Likewise, once the firm is contacted directly with a request for additional information, the Draft Guidance requires that the manufacturer's response to that original unsolicited off-label question

> occur solely between the firm and the individual who made the request. Regardless of the fact that the original, unsolicited off-label question may have been available to a very broad audience, the firm should not make its detailed response with off-label information publicly available within the same forum.

Thus, even when the public question is narrow, and regardless of whether it is asked in a live meeting or an online forum, the Draft Guidance essentially limits manufacturers from responding in that same public forum. Instead, the detailed off-label response must be made directly to the individual who requested the information.

With respect to nonpublic requests for information, the Draft Guidance requires that a firm actively seek to make narrower a broad request for information, such that the firm's response can be tailored to this narrower question. Questions regarding the use of a drug or device in connection with a particular off-label condition on which the manufacturer has no data cannot be responded to with information about other potentially related off-label conditions. Contrary to this restriction, however, the Draft Guidance actively requires that a firm provide, in response to questions concerning off-label uses about which it has no data, any data that it has describing a known or suspected risk associated with "other diseases or conditions" that may be relevant to the use of a drug or device described in the request. Other specific requirements described in the Draft Guidance detail what records must be kept of unsolicited requests and manufacturers' responses to such requests.

Comments on the Draft Guidance are requested by March 29, 2012, to ensure that they are able to be considered in the drafting of the final version.

New Docket Opened for Comments on Policy for Dissemination of Off-Label Information

Separate from the issuance of the Draft Guidance discussed above, FDA published a *Federal Register* notice announcing that it is accepting comments on scientific exchange about unapproved new uses of products that are already marketed, and uses of products still being investigated for initial approval. In the notice, FDA indicated that it opened this scientific exchange docket in response to a citizen petition it received from seven industry manufacturers that requested clarification on FDA's policies with respect to (i) manufacturer responses to unsolicited requests; (ii) scientific exchange; (iii) interactions with formulary committees, payors, and similar entities; and (iv) dissemination of clinical practice guidelines developed by third parties, such as healthcare organizations and institutions. FDA's notice

also indicated that it is considering a response on the issues raised, and that comments submitted to the docket on these matters would assist with the Agency's evaluation of its own policies in this regard.

Comments to this docket must be submitted by March 27, 2012.

How We Can Help

Morgan Lewis's FDA & Healthcare attorneys help clients design and implement programs for the development and review of promotional, nonpromotional, and scientific materials for dissemination to consumers and healthcare professionals. We routinely assist clients in assessing the regulatory compliance of these materials with FDA's policies, helping them interpret guidances and notices, such as those recently released, along with other technical laws and regulations. Additionally, our FDA & Healthcare attorneys help clients develop and implement training programs designed to increase their employees' understanding of, and compliance with, new regulatory requirements such as those outlined in the Draft Guidance. We also frequently assist clients in responding to FDA enforcement inquiries and correspondence, and in preparing and submitting comments to FDA's dockets on new matters, such as the scientific exchange docket discussed above.

If you would like further information regarding the issues raised in this Morgan Lewis LawFlash, please contact FDA & Healthcare attorneys **Alexis Reisin Miller** (202.739.5390; armiller@morganlewis.com) or **Kathleen Sanzo** (202.739.5209; ksanzo@morganlewis.com).

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